# Trimming Exposure Data, Putting Radiation Workers at Risk: Improving Disclosure and Consent Through a National Radiation Dose-Registry

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In the United States, regulatory standards allow workers to be exposed to ionizing radiation that can cause 1 additional cancer fatality per 400 workers per year. Because radiation-dose limits cover only single sources (e.g., a nuclear plant) or exposure classes (workplace, medical, or public) and are defined for average occupational exposure, workers typically do not know their precise cumulative, individual, and relative risks from radiation. Nevertheless, this information is necessary for informed consent, because most scientists say radiation effects are cumulative and linear with no risk threshold. To promote public health, informed consent, and better understanding of the effects of low-dose radiation, I argue for a multistage National Radiation-Dose Registry, beginning with cumulative, individual worker doses. (*Am J Public Health.* 2007;97:1782–1786. doi:10.2105/AJPH.2005.085027)

Current US regulatory standards allow workers to receive much higher doses of ionizing radiation than members of the public. For instance, licensed operators of nuclear power plants may annually expose workers to doses 50 times higher than those to which they expose the public. These differences are important because most scientists, including members of the influential 2005 National Academy of Sciences' Committee (to assess the biological effects of ionizing radiation), BEIR VII, say that "the most reasonable description" of the relation between low-dose radiation exposure and resulting health effects is that any radiation dose is risky and cumulative-hence that health effects are linear with no threshold (LNT).2

Although radiation effects vary among people—as a function of factors like genetics, age at exposure, sex, and coexposures—BEIR VII estimates that each 10 milliSieverts (mSv) per year of radiation exposure, for a 70-year lifetime, causes a 5% (lifetime) increase in fatal cancers, or about 1 additional fatal cancer per year for every 300 people exposed. Using a different data set, the International Commission on Radiological Protection (ICRP) arrived at a similar estimate. Every exposure to the maximum-allowable occupational radiation

dose—50 mSv per year—induces about 1 additional fatal cancer per year in every 500 people exposed.<sup>3</sup>

The largest study of nuclear workers to date (2005), conducted by the International Agency for Research on Cancer (IARC), implies an even higher risk-about 6 additional fatal cancers per year per 500 people exposed to the maximum-allowable occupational radiation dose of 50 mSv per year.4 According to the IARC study, although the average worker's exposure is relatively low (about 20 mSV cumulative radiation dose), 1% to 2% of the cohort's lifetime fatal cancers (roughly 4100 to 8100 cancers in 407 391 people) are attributable to these occupational doses. For comparison, the average US public exposure is about 3 mSv per year, roughly 80% from natural background radiation and 20% from humanmade sources.2

How many people receive occupational radiation exposures? In Canada, whose population is one tenth that of the United States, there are more than 550000 radiation workers in more than 80 occupations. These include not only nuclear workers (those employed in commercial nuclear-power generation or by those who build and test

nuclear weapons) but also radiation workers who are employed in academic research, food processing, industrial imaging, weld-defect inspection, leak tracing, automobile-steel testing, mineral-deposits discovery, and so on. In Switzerland, radiation workers number 60 000; in South Korea, 65 000. In the United States, 1.5 million radiation workers are occupationally exposed to ionizing radiation each year. Of this number, 300 000 nuclear workers are employed in the commercial nuclear industry.<sup>5</sup>

Obviously if radiation workers face higher health risks, they should know about these risks and consent to them. I argue that many workers probably cannot consent to these occupational risks and that, in principle, a national radiation-dose registry (RDR) could promote fuller dose disclosure and informed consent.

#### **FLAWED CONSENT**

Two factors that can block occupational consent to ionizing radiation are a lack of individualized radiation-dose data and a lack of cumulative radiation-dose data. Unlike some other developed nations that require workers to have personal air monitors, the United States has little individualized radiation-dose data because it allows employers to use general air monitors (single, fixed, air samplers for assessing internal radiation dose and regulatory compliance) and to report only mean radiation exposures in work areas.<sup>6</sup> Consequently reports of occupational radiation doses in the United States frequently underestimate exposures and mask uncertainties and variations in radionuclide concentrations and doses. In some workplaces, these concentrations change 4 orders of magnitude over 2 months and 3 orders of magnitude within a day.<sup>7</sup>

The National Council on Radiation Protection and Measurement warns that general air samplers can underestimate radionuclide concentrations by 3 orders of magnitude, especially if they are located far from the employees who receive the highest exposures. 8 Consequently, unless there are other means of assessing doses, radiation workers may be unable to know or consent to their precise, individual, radiation doses.

Lack of data on cumulative radiation doses likewise threatens occupational consent. Suppose 2 workers, 1 a cancer survivor who had received radiotherapy, and another who had not received it, were deciding whether to continue radiation work. If the risks from a given radiation exposure increase on a scale of the excess relative risk, as is often assumed, suppose both workers receive the same occupational dose.

However, according to the LNT model adopted in BEIR-VII, when expressed on a relative-risk scale,<sup>2</sup> risk differences associated with this same dose are larger at higher cumulative doses. All other things being equal, Hall<sup>9</sup> notes that the prior radiotherapy could give the first worker a 10-year average cancer risk that is 6 times higher than that of the second worker. Yet as the National Academy's BEIR VII report notes, depending on the type of cancer and therapy, a therapeutic radiation dose could be 200 to 1200 times greater than the maximum annual occupational dose of radiation.2 If so, this would give the first worker a cancer risk that is much higher than 6 times the cancer risk of the second worker.

Or, because about 60% of human-made radiation exposures are from medical x-rays, suppose the first worker had 1 whole-body computed tomography (CT) scan, with exposures of about 10 mSv.2 This would give him about half the cumulative radiation dose of the workers who were included in the IARC study,4 or one fifth of the US maximum-allowable annual occupational dose.1 A diagnostic abdominal helical-CT scan, performed in childhood, would increase the first worker's cancer risk about as much as receiving half the US maximum-allowable annual occupational dose of radiation; even x-rays taken as part of required worker health exams might contribute to radiation risk.10

Despite these 2 workers' radically different radiation-exposure histories, they probably

would not receive quantitative information about their different relative risks. Because all nations require employers to disclose only occupational radiation doses (those relevant to employer regulatory compliance), employees typically have incomplete or trimmed information about their individual, cumulative, and relative radiation doses and risks.<sup>7,3</sup>

Protection of US radiation workers thus relies on 1 type of information—average occupational dose—to achieve employer compliance with regulations. Achieving employee consent, however, also requires another type of information—individual cumulative dose.

All bioethics codes, like the famous Helsinki Declaration, require potential risk recipients to be adequately informed of, and to consent to, the risk.11 Implementing this requirement, the classic doctrine of informed consent mandates 4 necessary conditions. The risk imposer must fully disclose the risk; the risk recipients must fully understand the risk; they must be competent to assess the risk; and they must voluntarily accept the risk. 12 If the cumulative and individual radiation doses partly determine occupational-exposure risks, but workers know only the average occupational dose, obviously the risk disclosure is incomplete. Workers may misunderstand the different relative risks associated with the same average occupational dose of radiation.

Consider the 2 radiation workers in the previous example. Receiving the same occupational-radiation exposures, they are like 2 nighttime drivers on a foggy mountain road without a guardrail. The distance to the edge represents the odds ratio (which is linear) of getting radiation-related cancer, although cell sterilization and death may be more likely at high doses.<sup>2</sup> The edge represents malignancy, and the fog represents difficulties with radiation risk assessment and workers' understanding of their relative risks. The driver closer to the edge is like the higher-exposure worker who has accumulated all radiation hits except the last 1 required for malignant transformation. The driver farther from the edge is like the lower-exposure worker who has not accumulated these hits. If both drivers move 2 feet toward the edge (both workers get another hit), they may be unaware that the effects will not be the same for each of them.

Worker information and consent also are limited because ICRP and national laws mandate no overall radiation-dose and risk limits, only limits within single exposure classes (e.g., medical, occupational, public) and from single sources, like a nuclear power plant.<sup>3</sup> Consequently no nation routinely measures cumulative radiation dose and risk from all sources and all exposure classes, even for high-exposure workers.

Most nations also have not followed Canada and instituted a reliable, centralized dose registry for radiation workers. The United States has a variety of registries, 13 some run by groups alleged to have conflicts of interest, like the Department of Energy (DOE), the Nuclear Regulatory Commission, the Department of Veterans Affairs, and individual facilities. No one has systematically studied radiation-induced disease by combining and improving all US registries, partly because different groups control them. One result has been flawed occupational-dose data, difficulties in reconstructing doses under the energy workers' compensation act, inadequate occupational-dose disclosure and consent, repeated human and environmental contamination by radiation, and avoidable deaths, as in the case of hundreds of Navajo uraniumminer fatalities.14

In 1991, confirming contamination and radiation-dose falsification among 600 000 nuclear workers at 3500 US DOE facilities, the Office of Technology Assessment recommended DOE abolition or outside regulation. <sup>15</sup> Neither occurred. Again in 1994 and 1999, Congress criticized DOE and its contractors for radiation-safety violations, falsification of worker-dose records, contamination, and cover-up. <sup>16</sup> In 1998, the Government Accountability Office warned: "Widespread environmental contamination at DOE facilities . . . provides clear evidence that [DOE] self-regulation has failed." <sup>17</sup>

# THE PROPOSED RADIATION-DOSE REGISTRY

One remedy for repeated government criticism of US radiation-worker policies would be a reliable, centralized, independent (of agency conflicts of interest) RDR, perhaps in the US Centers for Disease Control and Pre-

vention. At a minimum, this RDR would include activities of centralized radiation-dose collection, epidemiological analysis, risk assessment, risk communication, and verification of dose measurement.

Creating an RDR would not by itself resolve most problems of radiation-dose accuracy. Excellent research traditions are also required, as at Japan's Radiation Research Effects Foundation.

A first step might be congressional hearings to evaluate an in-principle commitment to RDR. A second step might be building on BEIR work, commissioning a US National Research Council study of radiation epidemiology and charging it with developing scientific and practical recommendations for implementing a reliable RDR, perhaps modeled on the Canadian registry.<sup>5</sup> A third step might be implementing National Academy BEIR VII recommendations. A fourth step might be encouraging other nations to develop similar registries, as BEIR VII suggested. This fourth step would enlarge the radiation-data set and help resolve international controversies over radiation-dose fluctuations and uncertainties.

The needed academy scientific recommendations (second step) would include those for achieving accurate, complete data; learning from Canadian experience; improving on excellent studies such as the 2005 IARC; deciding which covariates—like smoking and dietary history—to include; evaluating confounders and effect modifiers; using meta-analysis and pooling to resolve controversies; and centralizing and improving data from existing general registries. The needed practical recommendations would include those for privacy, cost, liability, potential litigation, access to data, and similar registries in other nations.

The National Academy of Sciences is a logical place to develop RDR-implementation strategies, given that RDR is relevant to BEIR-VII goals. Recommending prospective collection of exposure data and citing the particular importance of nuclear-worker doses, BEIR-VII called for extensive radiation-epidemiological studies—including follow-ups of CT-scan cohorts—to resolve theoretical and practical problems of low-dose radiation. It also recommended global radiation consortia using similar methods of data collection and follow-up; individualized, real-time estimates of radiation doses; national radiation-worker registries; and

linking these registries with sets of other exposure data, including those in tumor and disease registries.<sup>2</sup> A reliable RDR would facilitate all of these BEIR VII recommendations.

Because reconstructing diagnostic and therapeutic radiation exposures is difficult, if not impossible, RDR data collection could be implemented in stages, beginning with data on occupational-radiation exposures. Following BEIR-VII recommendations, a second stage might add workers' medical-exposure data. At a third stage, the RDR might include medical and occupational radiation exposures for the entire US population. At a fourth stage, all fallout, accident, consumer-product, and other exposures for the US population might be added. The Centers for Disease Control and Prevention and National Cancer Institute web sites already reveal precedents for small parts of the RDR, like the National Cancer Institute's radiation-dose calculator; this online calculator lets citizens estimate their falloutrelated, iodine-131 thyroid doses.18

# ADDITIONAL ARGUMENTS FOR A RADIATION-DOSE REGISTRY

Besides promoting worker consent, a reliable RDR is necessary to implement current annual, 5-year, and lifetime radiation-dose limits within exposure classes. 1,3 Without an RDR, one could never know whether any of these allowable limits were exceeded, especially because workers can move among nuclear plants and accrue maximum-allowable annual radiation doses at several different plants. Some high-risk workers, "jumpers," work at several facilities each year. Without a registry, they bear sole responsibility for reporting past radiation exposures. The RDR also could clarify radiation-dose distribution among members of the public, providing sounder bases for regulation and for resolving scientific controversies.

A reliable RDR likewise could help improve direct, empirical information about the effects of low-dose radiation. This improvement is especially needed for 3 reasons. First, many current low-dose-radiation standards rely on imperfect cancer estimates obtained by extrapolating from epidemiological studies of higher doses and higher dose rates, like those that characterize the classic cohort of atomic bomb survivors.

Second, historically scientists have repeatedly shown the need to raise radiation-risk estimates.

Third, empirically derived radiation-dose data often conflict with extrapolated radiation-dose data. For instance, the 2005 IARC study has central risk estimates of cancer mortality that are 2 to 3 times higher than linear extrapolations from the data for atomic bomb survivors, although the IARC estimates are statistically compatible with the bomb estimates, given wide confidence intervals. Empirical data from the 2005 Techa cohort likewise has produced much higher estimates of excess relative risk than atomic bomb extrapolations have produced, but the Techa data also have problems with confidence intervals and dose estimates. <sup>19</sup>

The fact that the IARC and Techa studies found higher radiation-risk coefficients than are currently accepted is a good reason to promote the RDR and further radiation-risk assessment. At a minimum, such assessment needs to include accounting for diagnostic x-ray exposures; improving information and follow-up on vital status in the Techa cohort 19; and extending IARC results to females, because 90% of the cohort, and 98% of the collective radiation dose was to males.

An RDR also might help illuminate other controversies, like that over doses and confidence limits in Canadian worker research showing an excess relative cancer risk per 100 mSv that is 13 times higher than the radiation risk revealed by the atomic bomb study<sup>21</sup> and 33 times higher than the radiation risk revealed by the British worker study.22 By controlling for factors like confounders, healthy-worker effects, and dose misclassifications; providing direct, individualized, exposure data; offering larger samples and longer exposure periods; and building on worker studies,20 the RDR could facilitate exploratory data analysis, clarify low-dose controversies, make radiation studies cheaper and easier, and provide a model for other nations to follow.

#### **OBJECTIONS**

If, in principle, a US RDR is scientifically and ethically defensible, why has it not been adopted? Some objectors say employers

should not have to ensure that radiation employees are informed about and consent to occupational, cumulative, and relative radiation doses and risks, because employers have no control over nonoccupational risks.

Yet neoclassical economics recognizes both that the imposition of workplace risk requires employees' consent and their full receipt of information, and that economic efficiency obliges employers to help meet these requirements.<sup>23</sup> Ethics likewise requires employers to promote employee-risk disclosure, consent, and protection, because employers profit from employee radiation exposures; rights to profit entail corresponding responsibilities.<sup>24</sup> ICRP and many nations also recognize this employer responsibility, as illustrated by laws requiring employers both to monitor pregnant radiation workers and to take workers' medical histories.25

A second objection is that because the RDR could open highly exposed radiation workers to occupational discrimination, like that used against chemical industry employees with genetic predispositions to chemically induced disease, 26 radiation workers might avoid radiotherapy or diagnostic x-rays.

However, worse consequences (than occupational discrimination) could follow from allowing some individuals' fears of discrimination to trump everyone's rights to know and to consent to radiation risks. Allowing this trump would mean that fear of resulting mistreatment could be used to justify nonrecognition of any human right. Allowing this trump would mean that society could be guided by expediency and emotion, not by ethics and law. A better solution is working to protect victims of discrimination, as in cases of workplace mistreatment based on race, religion, or gender. Besides, just as radiation workers decide whether to report their pregnancies, and British nuclear employees sometimes can exclude their radiation doses from the registry,<sup>27</sup> employees might avoid potential discrimination by sometimes retaining rights not to disclose their nonoccupational radiation exposures.

A third objection is that someone might say the RDR is not needed because most occupational radiation exposures are low. However, if earlier IARC data are correct, many doses are not low.

About 400 IARC-cohort members received cumulative occupational radiation doses greater than 500 mSv, which BEIR-VII models say will cause at least 8 fatal cancers, and about 41 000 cohort members received cumulative occupational radiation doses greater than 50 mSv, which BEIR VII ties to 82 fatal cancers. Even the cumulative occupational dose for members of the IARC cohort, averaging about 20 mSv, will cause fatal cancer in more than 1 of every 250 workers.4

Earlier accounts of DOE's lax safeguards and occupational-dose falsification also suggest that some US worker doses might be high. Otherwise, why has the United States (with its 50-mSv-allowable-radiation dose per year) not adopted the stricter 20-mSv occupational standard of other nations, or the 12.5-mSv limit recommended by British authorities?<sup>28</sup>

Even if most US occupational radiation doses were low, this third objection errs in assuming that not everyone has rights to equal protection, that only utilitarian or majority protection is necessary-the greatest good for the greatest number of workers.<sup>29</sup> The objection also erroneously assumes that the size of the radiation dose alone is always sufficient to make doses ethically acceptable.

Described by British ethicist G.E. Moore,<sup>30</sup> this second error is known as the naturalistic fallacy. Those who commit this fallacy attempt to reduce ethical questions (e.g., is the imposition of workplace risk just?) to scientific questions (e.g., how high is workplace risk?). The 2 are irreducible because even small risks may be ethically unacceptable if they are easily preventable, imposed unfairly, without adequate compensation, parts of rights violations, and so on. Besides, risk bearers ultimately must judge whether risks are low-by giving or withholding their consent.

A fourth objection is that there is less reason for disclosing workers' full radiation doses and risks than for disclosing sometimes-larger risks-like smoking.

Epidemiologically, this is often correct. As already mentioned, risks like smoking are important covariates whose inclusion in the RDR is probably essential to accurate dose information. Ethically, however, disclosing alcohol or tobacco risks is less important than disclosing individual, cumulative, and relative risks associated with occupational radiation. Why?

Despite pressures like cigarette advertising, largely personal risks like smoking are more ethically legitimated than workplace radiation exposures, because they typically involve more personal choice, more informed consent, and greater individual control. However, occupational radiation risks often involve less personal choice, less informed consent, and less individual control, partly because of inadequate disclosure and the frequent absence of alternative employment options.<sup>31</sup>

Whenever risk imposition involves less choice, consent, and personal control, as in workplaces, even small risks can require more ethical and societal attention than larger risks that involve more choice, consent, and control.<sup>32</sup> Government also has greater duties to regulate risks that 1 party imposes on another than to regulate more self-chosen risks affecting mainly the chooser.

#### **CONCLUSIONS**

If science defines radiation risk as cumulative and LNT, and if workers have rights to know and to consent to radiation risks, society should ensure that workplace policies are consistent with its science, are consistent with its ethics, and do not jeopardize worker consent. In principle, a reliable RDR, implemented with National Research Council assistance, could help promote fuller radiation dose disclosure, which is essential to workplace consent.

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No human participants were involved in this study.

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